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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL S. WILLIAMS and
JOSEPH M. DESIMONE

Appeal 2009-006963
Application 10/662,757
Technology Center 1700

Decided: January 27, 2010

Before ADRIENE LEPIANE HANLON, CHUNG K. PAK, and
TERRY J. OWENS, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 73-104, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The Appellants claim a method for impregnating an intraluminal prosthesis. Claim 73 is illustrative:

73. A method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:

immersing an intraluminal prosthesis in a mixture of a carrier fluid and a pharmacological agent, wherein the intraluminal prosthesis comprises non-layered polymeric material;

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the non-layered polymeric material;

removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient, wherein the concentration gradient defines an elution profile of the pharmacological agent from the non-layered polymeric material when the intraluminal prosthesis is deployed within a body of a subject.

The References

Guruwaiya	6,251,136 B1	Jun. 26, 2001
Ragheb	6,299,604 B1	Oct. 9, 2001
Edwards	6,670,398 B2	Dec. 30, 2003
	(effective filing date on or before Oct. 25, 2001)	
Greiner	EP 0 405 284 A2	Jan. 2, 1991
Mehta	WO 01/87368 A1	Nov. 22, 2001
Igaki (as translated)	WO 02/43799	Jun. 6, 2002

The Rejections

The claims stand rejected under 35 U.S.C. § 103 as follows:

claims 73, 74, 76, 80-84 and 86 over Igaki; claims 75, 99-101 and 104 over Igaki in view of Guruwaiya; claims 73, 74, 76-78, 80-82, 86, 88, 89, 91-93

and 98 over Greiner; claims 75, 90 and 99-104 over Greiner in view of Guruwaiya; claim 79 over Igaki in view of Edwards; claims 79 and 95 over Greiner in view of Edwards; claims 81, 83, 84, 86, 93, 94, 96 and 98 over Greiner in view of Igaki; claims 85 and 97 over Greiner in view of Mehta; claim 87 over Igaki in view of Ragheb; and claim 87 over Greiner in view of Ragheb.[1]

OPINION

We affirm the Examiner's rejections.

Issue

Have the Appellants shown reversible error in the Examiner's determination that 1) the removal of pressure by Igaki or Greiner inherently forms a concentration gradient, or 2) Igaki would have rendered prima facie obvious, to one of ordinary skill in the art, impregnating a polymeric material which has been coated onto a portion of an intraluminal prosthesis (claim 86)?

Findings of Fact

Igaki discloses a blood vessel stent in which a biodegradable polymer is swollen by keeping the biodegradable polymer and a drug together for a specified time in a supercritical fluid such that the drug is supported on the swollen biodegradable material (p. 5). The biodegradable polymer can be a coating on the stent surface (p. 6). The supercritical fluid can be CO_2 (p. 13). The supercritical fluid is gradually discharged to bring the chamber to atmospheric pressure such that the supporting of the drug on the stent is completed (p. 14).

[1] A rejection of claims 86 and 98 under 35 U.S.C. § 103 over Greiner is withdrawn in the Examiner/s Answer (Ans. 2).

> Greiner discloses
>
> a method of impregnating a catheter, made of a polymeric material, with a pharmaceutical comprising the steps of immersing the catheter into a saturated solution of a pharmaceutical in a pharmaceutically acceptable solvent, contacting the catheter at or near supercritical pressure and temperature conditions of the solvent with the saturated solution, and reducing the pressure from the supercritical pressure condition to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated into the catheter. [col. 1, l. 52 – col. 2, l. 8].

After that contacting, "the volatile swelling agent is separated from the catheter, leaving the pharmaceutical behind. Because of the volatility of the swelling agents employed, separation is easily accomplished by lowering the pressure" (col. 4, ll. 2-6). The preferred solvents include CO_2 (col. 3, ll. 17-18).[2]

Analysis

The Appellants argue that US 2003/0104030, which the Examiner had relied upon as an English language equivalent of Igaki until this appeal, discloses at paragraph 0062 that "[t]he drug 26 is now fully impregnated in the stent 1 to complete the luminal stent according to the present invention" (Br. 8). The corresponding sentence in the Igaki translation relied upon by the Examiner in this appeal reads: "As a result, the support of the drug agent 26 on the stent 1 will be completed, and it will be possible to obtain the stent for a blood vessel according to the present invention" (p. 14). The Appellants argue that one of ordinary skill in the art would not have

[2] The Appellants do not provide a substantive argument as to the separate patentability of the claims to which Guruwaiya, Edwards, Mehta and Ragheb are applied (Br. 16-27). We therefore need not further address those references.

interpreted "fully impregnated" as meaning that a concentration gradient is formed (Br. 8-9). The Appellants argue that Igaki's figures, Table 3 and examples disclose only an amount of impregnated drug, not a gradient, and that Igaki does not teach or suggest controlling variables such as temperature and pressure to obtain a gradient (Br. 9; Reply Br. 3-4).

The Examiner argues (Ans. 11):

> Igaki teaches that the supercritical CO_2 pressure within the reaction chamber 27 is gradually discharged to bring the chamber to atmospheric pressure (first full paragraph on pg. 14). The rate of pressure change is controlled in the process of Igaki since the pressure is "gradually" released. Because a concentration gradient is created in the present invention when the rate of pressure change is controlled, such a phenomenon must also necessarily occur in the method of Igaki due to the controlled release of pressure.

The Appellants argue that "[t]his is mere speculation on the Examiner's part and there is no fact or technical reasoning provided in support of this statement, as required to demonstrate that the methods of the claimed invention are inherently disclosed in the Igaki reference" (Br. 11).

When an examiner relies upon a theory of inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990). The Examiner has provided such a basis in technical reasoning, i.e., because, like the Appellants, Igaki gradually reduces the supercritical fluid pressure, there is reason to believe that, like the Appellants, Igaki forms a concentration gradient.

As stated in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. [citation omitted] Whether the rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

The Appellants have not provided that proof.

The Appellants argue that Igaki discloses controlling the drug release time only by the use of layers of biogradable material (Br. 11).

That argument is not relevant to the Examiner's basis for rejection.

The Appellants argue regarding claim 86 that "there is no teaching or suggestion in Igaki that the polymeric material is a coating on a portion of the intraluminal prosthesis as recited in Claim 86 of the present invention" (Br. 12).

That suggestion is on page 6 of Igaki: "A drug agent can be contained within the biodegradable polymer layer that is applied as a coating onto the surface of the stent."

With respect to Greiner the Appellants argue that only impregnation with specific concentrations, not concentration gradients, of a drug is disclosed (Br. 13-14).

The Examiner argues (Ans. 13):

> Greiner teaches that the pressure is lowered (col. 4, lines 2-6) and that the reactor is depressurized after the impregnating step (col. 5, lines 18-25). The pressure must necessarily be released at some rate in order to lower the pressure in the chamber, resulting in a rate of pressure change within the chamber. The pressure is lowered in some

> predetermined manner and, thus, the rate of release must necessarily be controlled to some degree. Because a concentration gradient is created in the present invention when the rate of pressure change is controlled and unless critical steps are missing, such a phenomenon must also necessarily occur in the method of Greiner due to the controlled release of the pressure.

Thus, the Examiner has provided plausible technical reasoning as to why, like the Appellants' controlled pressure reduction, Greiner's pressure reduction produces a concentration gradient.

The Appellants argue that the Examiner "contends that '[t]here must be some control of how fast the rate of pressure changes' (*Id.* [Final Rejection mailed Feb. 12, 2008, p. 5]) but does not provide any evidence for such a supposition" (Br. 14).

The Appellants state that "[t]he step of removing pressure is carried out under controlled conditions after a predetermined time and according to a predetermined schedule to insure that the desired predetermined amount of the pharmacological agent remains" (Spec. 16:17-22). Because, like the Appellants' pressure reduction, Greiner's pressure reduction leaves a desired amount of pharmacological agent remaining (col. 2, ll. 5-8; col. 4, ll. 2-4), it appears that, like the Appellants' pressure reduction, Greiner's pressure reduction is carried out under controlled conditions. The Appellants have provided no evidence or reasoning to the contrary.

Conclusion of Law

The Appellants have not shown reversible error in the Examiner's determination that 1) the removal of pressure by Igaki or Greiner inherently forms a concentration gradient, or 2) Igaki would have rendered prima facie obvious, to one of ordinary skill in the art, impregnating a polymeric

material which has been coated onto a portion of an intraluminal prosthesis (claim 86).

DECISION/ORDER

The rejections under 35 U.S.C. § 103 of claims 73, 74, 76, 80-84 and 86 over Igaki, claims 75, 99-101 and 104 over Igaki in view of Guruwaiya, claims 73, 74, 76-78, 80-82, 86, 88, 89, 91-93 and 98 over Greiner, claims 75, 90 and 99-104 over Greiner in view of Guruwaiya, claim 79 over Igaki in view of Edwards, claims 79 and 95 over Greiner in view of Edwards, claims 81, 83, 84, 86, 93, 94, 96 and 98 over Greiner in view of Igaki, claims 85 and 97 over Greiner in view of Mehta, claim 87 over Igaki in view of Ragheb, and claim 87 over Greiner in view of Ragheb are affirmed.

It is ordered that the Examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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